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09/678,579	10/03/2000	Daniel A. Japuntich	48317USA3H.027	7369

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EXAMINER

LEWIS, AARON J

ART UNIT	PAPER NUMBER
3761	12

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/678,579	Applicant(s) DANIEL A. JAPUNTICH
Examiner AARON J. LEWIS	Art Unit 3761



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Sep 11, 2002

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 33-71 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 33-71 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____	6) <input type="checkbox"/> Other: _____

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DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 33-71 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 34-38,40-74,78-81 of copending Application No. 08/240,877. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in each co-pending application are drawn to a filtering face mask adapted to fit over the nose and mouth of a wearer and having an

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exhalation valve which has a flap retaining stationary surface and a second free portion which lifts away from its seat during user exhalation. While certain features (e.g. a filtering layer for filtering air that passes through the mask body; flap retaining surface and the seal surface being non-aligned and positioned relative to each other to allow for a cross-sectional curvature of at least the one free portion of the flexible flap when viewed from the side in a closed position, the non-alignment and relative positioning of the flap-retaining surface and the seal surface also allowing for the one free portion of the flexible flap to be pressed against the seal surface when a wearer of the mask is neither inhaling nor exhaling) are omitted from base claims 33 and 63 of the instant application, the mere omission of an element and its function (e.g. a filtering layer for filtering air that passes through the mask body; flap retaining surface and the seal surface being non-aligned and positioned relative to each other to allow for a cross-sectional curvature of at least the one free portion of the flexible flap when viewed from the side in a closed position, the non-alignment and relative positioning of the flap-retaining surface and the seal surface also allowing for the one free portion of the flexible flap to be pressed against the seal surface when a wearer of the mask is neither inhaling nor exhaling) is an obvious expedient if the remaining elements perform the same function as before. In re Karlson, 136 USPQ 184 (CCPA 1963). Also note Ex parte Rainu, 168 USPQ 375 (Bd. App. 1969). Omission of a reference element whose function is not needed would have been obvious to one of ordinary skill in the art..

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 33-56,63-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simpson et al.('516) in view of McKim ('618), for the reasons set forth on pages 2-6 of the Office action dated 07/06/01.

As to claim 63, Simpson et al. as modified by McKim as discussed above with respect to claim 33, also teach the flexible flap being positioned on the valve seat such that the flap is pressed towards the seal surface in an abutting relationship therewith when a fluid is not passing through the orifice (page 2, lines 39-42 of Simpson et al. which expressly discloses that the valve flap (13) of fig. 2 is arranged to cover the orifice during inhalation). Inhaled air enters the interior of the mask (fig.1) through the filter material of the body of the mask and exhaled air exits the interior of the mask of Simpson et al. via the exhalation valve (fig.2). Simpson et al. disclose the use of the mask in environments which have noxious fumes present; consequently, given the manner of operation of the filtering mask and exhalation valve, in order for it to protect a wearer from noxious fumes, it stands to reason that the exhalation valve remains closed in all physical orientations (i.e. the exhalation valve body is pressed towards the seal surface in an abutting relationship when (during inhalation) fluid is not passing through the orifice (16)) except during

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user exhalation. Otherwise, resort is had to McKim (figs.1 and 3) which teach a valve which is pressed towards the seal surface in abutting relationship therewith under any orientation of the valve when no external forces from the movement of fluid are exerted upon the flap.

As to claims 64 and 65, the particular material from which the valve seat of Simpson et al. is made and the manner of making the valve seat can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular material nor in the manner of making the seat. It is noted that Simpson et al. (page 2, line 39) discloses that the valve flap being made from a plastic material. It is submitted that it would have been obvious to make the valve seat from any well known material including plastic by any well known method including injection molding because it (the valve seat) would physically cooperate more effectively with a valve flap of the same material than one made from a different material.

As to claims 66-69, McKim (fig.3) teaches a valve seat which includes a planar flap retaining surface that has two securement points associated therewith, the flap retaining surface also being positioned on the valve seat to allow the flap to be pressed in an abutting relationship to the seal surface when fluid is not passing through the orifice (col.1, lines 60-72 and col.2, lines 23-28).

5. Claim 57 is rejected under 35 U.S.C. 103(a) as being unpatentable over Simpson et al. in view of McKim as applied to claims 33-56,63-69 above, and further in view of Shindel ('277).

The difference between Simpson et al. and claim 57 is the inclusion of a valve cover, the flexible flap being held in position on the valve seat by mechanical means.

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Shindel (col.2, lines 59-66) teaches a valve securing device in the form of a valve cover (7) that is disposed over the valve seat and that comprises a surface (14) that mechanically holds flexible flap (6) against the flap retaining surface (5). Shindel cites the advantages of simplicity of arrangement and ready removability of the cover when desired which would allow for replacement and/or cleaning of the valve and orifices.

It would have been obvious to modify the manner of attachment of the exhalation valve of Simpson et al. to employ a cover over the valve seat because it would have provided a simple arrangement with ready removability of the cover when desired and because it would have provided protection for the exhalation valve as taught by Shindel.

6. Claims 58-62,70,71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simpson et al. in view of McKim as applied to claims 33-56,63-69 and further in view of Warbasse ('706) and Braun ('362).

The differences between Simpson et al. and claim 58 are a valve cover having a fluid impermeable ceiling that increases in height in the direction of the flexible flap from the first end to the second end and cross members that are disposed within the opening of the valve cover.

Warbasse teaches a valve cover (11) having a fluid impermeable ceiling that increases in height in the direction of the flexible flap from the first end to the second end for the purposes of protecting the valve flap (12), controlling the extent of movement of the valve flap, and controlling the direction of fluid flow exiting the mask via the valve.

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It would have been obvious to modify the valve (fig.2) of Simpson et al. to provide a valve cover because it would have provided a means for protecting the valve flap (12), controlling the extent of movement of the valve flap, and controlling the direction of fluid flow exiting the mask via the valve as taught by Warbasse.

Braun, in an exhalation valve for a filtering face mask, teaches cross members (19,20) which are slightly recessed beneath the seal surface (18) for the purpose of increasing the sealing force (col.4, lines 36-41) and cross members (25) that are disposed within the opening of the valve cover for the purpose of protecting the valve against debris (col.4, lines 25-26).

It would have been obvious to modify the cross members of Simpson et al. (structure through which openings 16 extend) to recess them slightly beneath the seal surface because it would have provided a increased sealing force as taught by Braun.

As to claim 59, Warbasse teach a valve cover (11 of fig.2) having an opening in the valve cover which is approximately parallel to the path traced by the second end of the flexible flap during its opening and closing.

As to claim 60, Simpson et al. as further modified by Warbasse teach a cover which directs exhaled downwards when the mask is worn by a person.

As to claim 61, the cover (#11 of figs.2 and 3) of Warbasse shows fluid impermeable sidewalls.

As to claim 62, the opening in the cover of Simpson et al. as modified by Warbasse is at least the size of the orifice in the valve seat as illustrated in figs.3 and 4 of Simpson et al..

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As to claim 70, the valve seat of Simpson et al. as modified by McKim and as further modified by Braun teaches a valve seat including a seal ridge (18 of Braun), onto which a seal surface is disposed, and a flap retaining surface, onto which the two securement points are located, the flap retaining surface being positioned on the valve seat to allow the flap to be pressed in an abutting relationship to the seal surface when a fluid is not passing through the valve (as discussed above with respect to claim 63 and with respect to claims 66-69).

As to claim 71, the two securement points of Simpson et al. as modified by McKim are located outside a region encompassed by the orifice (see fig.3 of McKim and fig.2 of Simpson et al.).

Response to Arguments

7. Applicant's arguments with respect to claims 58-62 have been considered but are moot in view of the new ground(s) of rejection.
8. Applicant's arguments filed 10/15/01 regarding claims 33-57,63-71 have been fully considered but they are not persuasive.

Applicant's arguments hinge on speculation of a possibility that valve flap (15) of Simpson et al. might "droop" away from the valve seat. There is no support in the disclosure of Simpson et al. which forms a basis for such a position. The mask body of Simpson et al. (fig.1) is disclosed as filtering inhaled air and releasing exhaled air through exhalation valve (fig.2). The mask of Simpson et al. is disclosed as being worn by persons in which the ambient atmosphere contains gaseous or vaporous contaminants (page 1, lines 24-28). In order for the mask of Simpson et al. to function as it is intended (and there is no reason to even suspect that it does not), the

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exhalation valve (fig.2) must remain closed until a wearer exhales; otherwise, gaseous or vaporous contaminants would leak into the interior of the mask body and be inhaled by such a wearer.

Applicant is reminded that the language of each of claims 33 and 63 requires only that the valve flap be pressed towards the seal surface in an abutting relationship therewith when a fluid is not passing through the orifice. As discussed above with respect to claim 33, Simpson et al. teach such an arrangement during a wearer's inhalation period. That is, even if the valve flap (15) of Simpson et al. were to "droop" away from its seat during a period of time when a wearer is neither inhaling nor exhaling, there is at least A time period (i.e. inhalation) during which no fluid is flowing through orifice (16) simultaneous with the valve flap (15) being pressed in an abutting relationship with the valve seat.

The Castiglione Affidavit is based upon the stated assertion (e.g. page 2, paragraph #9) that the valve flap (15) is not pressed into abutting relationship with the valve seat when a wearer is neither inhaling nor exhaling. While such may be the case, there is no objective evidence (e.g. a physical test of the mask disclosed by Simpson et al.) to support such a conclusion. Consequently, the affidavit is not persuasive.

9. Applicant's arguments filed 04/02/2002 have been fully considered but they are not persuasive.

Applicant's arguments regarding the propriety of the combination of prior art to Simpson et al. and McKim are disagreed with. Inasmuch as the valve flap of McKim lifts from the valve seat

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responsive to the pressure of the fluid passing therethrough and reseats due to its resilience, it does exhibit flexibility. Applicant's arguments alleging that one of ordinary skill would not consult consult reed valves for high speed engines may be accurate; however, the fact that McKim teaches the mounting of a valve flap in a curved orientation for the expressed purpose of increasing the efficiency of the seal between the valve flap and valve seat is seen as relevant information to one of ordinary skill in the creation of a more efficient seal between a valve and seat in any environment including the environment of valves in the respiratory arts.

10. Applicant's arguments filed 09/11/2002 have been fully considered but they are not persuasive.

The Bowers, Fabin and Betts Affidavits have been considered but are not persuasive for the following reasons: Applicants' argument that McKim constitutes nonanalogous art because it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, it is submitted that one of ordinary skill would look to the art of valves (which includes McKim ('618)) to address problems associated with the effectiveness of valve seating of a valve element which is used for controlling the direction of flow of breathable air through such a valve. McKim clearly addresses the problem of effectiveness of valve seating by non-aligning the flap retaining surface and the seal surface

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relative to each other thereby providing effective seating without float or bounce after each opening (col.1, lines 64-72).

Applicants' argument that the valve of McKim lacks the required flexibility of applicant's invention is disagreed with because McKim (figs.1 and 3) illustrates flexibility of the valve flap (14). Further, the manner of bending illustrated in figs.1 and 3 of McKim is consistent with appellants definition of a "...the flap can form or bend in the form of a self-supporting arc when secured at one end as a cantilever and view from a side elevation...". Finally, no particular degree of flexibility is quantitatively and/or structurally defined in any manner which is unobvious over the prior art combination of Simpson et al. as modified by McKim.

Applicants' assertion that the examiner has not provided any teaching, suggestion or motivation to combine the prior art to Simpson et al. and McKim is not accurate. As set forth above in the body of the rejection, the reason for combination of Simpson et al. with McKim is because it would have provided for quick effective seating without float or bounce after each opening as taught by McKim (col.1, lines 64-72).

Applicants' assertion that Simpson et al. and McKim each present very good evidence of a lack of motivation to combine their respective teachings because no one of ordinary skill in the respirator art has made use of the teachings of McKim in making an exhalation valve is not accurate because examples of the use of the manner of mounting valves as taught by McKim do exist in the respirator art. The mounting of flapper valves in the respirator art by clamping a stationary portion of the flap in a different plane than the sealing surface (i.e. seat) resulting in a

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curved configuration which physically biases a free end of the valve to a closed position is well known (see fig.3 of Simpson et al.). Another example is seen in the prior art to Matheson (cited but not applied) U.S. Patent 2,999,498, fig.8 and col.1, lines 38-46.

Applicants' argument that the prior art fails to teach or suggest the advantages of applicant's can provide is disagreed with because appellant is arguing against the references individually and one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicants' argument that the examiner has not provided a reason for combining Warbasse with Simpson et al. is not accurate. As stated herein above in the body of the rejection, it would have been obvious to modify the valve (fig.2) of Simpson et al. to provide a valve cover because it would have provided a means for protecting the valve flap (12), controlling the extent of movement of the valve flap, and controlling the direction of fluid flow exiting the mask via the valve as taught by Warbasse. This reason is drawn from the overall teachings of Warbasse. It is neither merely a conclusory statement nor a subjective belief.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron J. Lewis whose telephone number is (703) 308-0716.

Aaron J. Lewis

December 29, 2002



Aaron J. Lewis
Primary Examiner